K003098

NOV 2 0 2000

BECKMAN COULTER

510(k) Summary
Prepared 29 September 2000

Applicant's Name and Address

Beckman Coulter, Inc.
P.O. Box 269006
San Diego, CA 92196-9006

Contact Person: Mara Caler
858 621 4583

Alternate Contact Person: Brent Tabor
612 448 4848

Device Name

Trade Name - Access® Ultrasensitive hGH Calibrators on the Access® Immunoassay Systems
Common Name – hGH Calibrators
Classification name – Calibrators (21 CFR 862.1150)

Predicate Device

Beckman Coulter Synchron Systems LX PAB Calibrator, K994168

Device Description

The Access® Ultrasensitive hGH Calibrators are lyophilized Calibrators to be used with the Access Immunoassay System.

Intended Use

The Access Ultrasensitive hGH Calibrators set is a device intended for medical purposes for use in the Access Immunoassay System, to establish points of reference that are used in the determination of values in the measurement of human growth hormone (hGH) levels in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2000

Ms. Mara Caler
Regulatory Specialist
Beckman Coulter, Inc.
PO Box 269006
7330 Carroll Road
San Diego, California 92196-9006

Re: K003098
Trade Name: Access® Ultrasensitive hGH Calibrators
Regulatory Class: II
Product Code: JIT
Dated: September 29, 2000
Received: October 3, 2000

Dear Ms. Caler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003098

Device Name: Access® Ultrasensitive hGH Calibrators

Indications For Use:

The Access Ultrasensitive hGH Calibrators set is a device intended for medical purposes for use in the Access Immunoassay System, to establish points of reference that are used in the determination of values in the measurement of human growth hormone (hGH) levels in human serum and plasma.

21 CFR 862.1150 Calibrator

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

(b) *Classification.* Class II.

(Division Sign-Off)
Division of Clinical Lab... ...ice...
510(k) Number K003098

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)